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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/972,794	10/05/2001	Andrea Amalfitano	5405-232DV	5221
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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/972,794**

Applicant(s)  
**Amalfitano**

Examiner  
**Dave Nguyen**

Art Unit  
**1632**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-148 and 207-246 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-148, 207-246 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 9, 25-43, 59, 68-71, 75-77, 87-92, 99-108, 117-118, 122-124, 132, 133, 146-148, 223-224, 227, 229-236, drawn to a propagation-defective adenovirus or adenovirus based vector comprising an adenovirus genome which has a deletion in the Iva2 region of the genome, cells comprising the adenovirus or vector, method of making the virus or vector, classifiable in class 435, subclass 320.1, 91.4, 325, 455, and class 424, subclass 93.2.
- II. Claims 1-5, 12-16, 25-43, 59, 67-71, 75-86, 93-98, 105-108, 110-116, 132-133, 146-148, 207-209, 213-222, drawn to a propagation-defective adenovirus or adenovirus based vector comprising an adenovirus genome which has a deletion in the 100 region of the genome, cells comprising the adenovirus or vector, method of making the virus or vector, classifiable in class 435, subclass 320.1, 91.4, 325, 455, and class 424, subclass 93.2.
- III. Claims 1-5, 17-19, 25-43, 59, 61-65, 69-71, 75-77, 105-108, 125-126, 128-130, 132, 133, 146-148, drawn to a propagation-defective adenovirus or adenovirus based vector comprising an adenovirus genome which has a deletion in the preterminal protein region of the genome, cells comprising the adenovirus or vector, method of making the virus or vector, classifiable in class 435, subclass 320.1, 91.4, 325, 455, and class 424, subclass 93.2.
- IV. Claims 44-49, 57-60, 63-66, 72-77, 134-141, 143-148, drawn to a propagation-defective adenovirus or adenovirus based vector comprising an adenovirus genome which has a deletion in the polymerase region of the genome, cells comprising the adenovirus or vector, method of making the virus or vector, classifiable in class 435, subclass 320.1, 91.4, 325, 455, and class 424, subclass 93.2.

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V. Claims 8, 10, 11, 51, 68, 104(b), 109, 119-121, 225, 228, drawn to a propagation-defective adenovirus or adenovirus based vector comprising an adenovirus genome which has a deletion in the Iva2 region and the polymerase region of the genome, cells comprising the adenovirus or vector, method of making the virus or vector, classifiable in class 435, subclass 320.1, 91.4, 325, 455, and class 424, subclass 93.2.

Claims 1(b), 44, 59(a), 102, 103, 105(a), 117, 223 are linking claims and will be examined to the extent that the claims embraces the claimed subject matter of the elected group.

VI. Claims 20-24, 52, 62, 109, 127, 142, drawn to a propagation-defective adenovirus or adenovirus based vector comprising an adenovirus genome which has a deletion in the polymerase region and the preterminal protein region of the genome, cells comprising the adenovirus or vector, method of making the virus or vector, classifiable in class 435, subclass 320.1, 91.4, 325, 455, and class 424, subclass 93.2.

Claims 1(c), 17, 44, 59, 105(c), 125, 134 are linking claims and will be examined to the extent that the claims embraces the claimed subject matter of the elected group.

VII. Claims 50, 109, 211, drawn to a propagation-defective adenovirus or adenovirus based vector comprising an adenovirus genome which has a deletion in the 100K region and the polymerase region of the genome, cells comprising the adenovirus or vector, method of making the virus or vector, classifiable in class 435, subclass 320.1, 91.4, 325, 455, and class 424, subclass 93.2.

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Claims 1(b), 105(a), 207 are linking claims and will be examined to the extent that the claims embrace the claimed subject matter of the elected group.

- VIII. Claims 210, drawn to a propagation-defective adenovirus or adenovirus based vector comprising an adenovirus genome which has a deletion in the 100K region and the Iva2 region of the genome, cells comprising the adenovirus or vector, method of making the virus or vector, classifiable in class 435, subclass 320.1, 91.4, 325, 455, and class 424, subclass 93.2.

Claim 207 is a linking claim and will be examined to the extent that the claim embraces the claimed subject matter of the elected group.

- IX. Claim 17, 104(c), 104(d), 226, drawn to a propagation-defective adenovirus or adenovirus based vector comprising an adenovirus genome which has a deletion in the Iva2 region and the preterminal protein of the genome, cells comprising the adenovirus or vector, method of making the virus or vector, classifiable in class 435, subclass 320.1, 91.4, 325, 455, and class 424, subclass 93.2.

Claims 1(b), 102, 103, 223 are linking claims and will be examined to the extent that the claims embrace the claimed subject matter of the elected group.

- X. Claims 17, 212, drawn to a propagation-defective adenovirus or adenovirus based vector comprising an adenovirus genome which has a deletion in the 100K region and the preterminal protein region of the genome, cells comprising the adenovirus or vector, method of making the virus or vector, classifiable in class 435, subclass 320.1, 91.4, 325, 455, and class 424, subclass 93.2.

Claims 1(a), 207 are linking claims and will be examined to the extent that the claims embrace the claimed subject matter of the elected group.

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- XI. Claims 20-24, drawn to a propagation-defective adenovirus or adenovirus based vector comprising an adenovirus genome which has a deletion in the 100K region, the preterminal protein region and the polymerase region of the genome, cells comprising the adenovirus or vector, method of making the virus or vector, classifiable in class 435, subclass 320.1, 91.4, 325, 455, and class 424, subclass 93.2.

Claims 1(a), 17 are linking claims and will be examined to the extent that the claims embraces the claimed subject matter of the elected group.

- XII. Claims 20-24, 119, drawn to a propagation-defective adenovirus or adenovirus based vector comprising an adenovirus genome which has a deletion in the Iva2 region, the preterminal protein region and the polymerase region of the genome, cells comprising the adenovirus or vector, method of making the virus or vector, classifiable in class 435, subclass 320.1, 91.4, 325, 455, and class 424, subclass 93.2.

Claims 1(b), 17, 105(c), 117 are linking claims and will be examined to the extent that the claims embraces the claimed subject matter of the elected group.

Note that the restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), as listed above. Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such (claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971).

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See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Groups I-XII are independent and distinct from one another, because an adenovirus genome which has a deletion in the 100K region is not the same as an adenovirus genome which has a deletion in the IvA2 region, polymerase region, or preterminal protein region. A search of one particular adenovirus based genome that has a particular deletion of a particular region does not necessarily overlap with that of another adenovirus based genome having another deletion of any other region. In addition, cells that expresses IvA2 is structurally distinct from cells that expresses 100K region, polymerase region, or preterminal protein region of an adenovirus. Furthermore, an adenovirus genome which has a deletion in the IvA2 region or a cell that expresses IvA2 is not limited for use in the making of the adenovirus based genome and/or vectors comprising a modified adenovirus genome having a deletion of any other region such as the polymerase region, the 100K region, or preterminal protein, and in fact can be used in a method of delivering an exogenous gene to a cell. In addition, cells that express IvA2 is not required to express 100K or preterminal protein or polymerase, and can be used to expresses adenoviral E1, for example. In addition, the combination of IvA2 and E1 or polymerase does not require the particular deletion of the preterminal protein region and/or the 100K region for patentability. Likewise, the combination of IvA2 and the 100K does require the particular deletion of the polymerase region and/or the preterminal protein region for patentability.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, and because of an enormous number of claims present in the as-filed application, and because of limited resources provided by the USPTO, it would be unduly burdensome for the examiner to search and examine for patentability of all of the claimed inventions, and thus, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election

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of the invention to be examined even though the requirement be traversed.


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen  
Primary Examiner  
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DAVE T. NGUYEN  
PRIMARY EXAMINER